B2

--6. (Amended) The method of claim 1 wherein the composition is in the form of a pharmaceutically acceptable saline solution, salve, or creme.--

B3

--11. (Amended) The method of claim 1 wherein the Human Immunodeficiency Virus is HIV-1 or HIV-2.--

REMARKS

Examiners Moezie's and Hui's courtesy and cooperation in a personal interview on June 21, 2001 with the inventor Dr. Claudia Stewart and the undersigned attorney is appreciated. As a result of the foregoing amendment, the claims have been modified in a manner as discussed in the interview.

As a result of the foregoing amendment, claim 1 has been amended in the manner suggested by the examiner to insert the word "prophylaxis" in place of the word "prevention". Additionally, claim 6 has been amended to delete the objected to phrase and claim 11 has been amended to correct a typographical error.

It is submitted that the rejection of the claims under the second paragraph of 35 U.S.C. § 112 has now been avoided. With respect to the examiner's rejection of claim 12, it is submitted that the recitation of "Compound 96" is definite and complies with the statute. Thus, the specification clearly indicates what Compound 96 is as shown in the table on page 6 of the specification. Consequently, referring to this compound as "Compound 96" does not introduce any indefiniteness into the claim since there can be no question as to what compound is meant. Thus, for example, in example 2, it is clear that Compound 96 is being used for the test shown therein. One skilled in the art would fully

OK ✓

understand what is meant and the objection to this claim on this basis should be withdrawn.

Reconsideration and withdrawal of the rejection of claims 1-14 as being unpatentable under 35 U.S.C. § 103 over the Dori WO '140 in view of Cooper et al '359 are respectfully requested.

The examiner asserts that Dori teaches a method for treating viral infection broadly by topically administering metallo-organic cobalt compounds including compound number 96. The examiner recognizes that Dori does not disclose a method for prevention or prophylaxis of HIV infection by topically applying the metallo-organic cobalt compound number 96 as recited in the present claims. Dori also does not teach using a condom for topical application.

It appears that it is the examiner's position however that Dori teaches a method for treating any viral infection by topical administration of the metallo-organic cobalt compounds and that Cooper et al teaches the use of a condom as an applicator. The examiner concludes that it would be obvious to one of ordinary skill from this disclosure to topically administer the present compounds for the prevention of prophylaxis of HIV infection. The examiner further asserts that one of ordinary skill in the art would have been motivated to utilize Compound 96 for prophylaxis since the compounds were known to be effective in treating viral infections and that one would expect the same compounds to be useful in treating any viral infections including those caused by HIV strains.

No basis exists in the cited art which supports the examiner's assertions and conclusions. Thus, the Dori et al reference says absolutely nothing about treatment of HIV. It is well known that Human Immunodeficiency virus is becoming scourge on the human race. While certain compounds have been promoted for use in treatment of patients having the disease, there is little if any promotion of any compound for use as a prophylactic agent with respect to this virus. Certainly, as the examiner correctly surmises, the Dori reference fails to teach a method for prophylaxis of HIV. Rather, Dori is concerned only with the treatment of patients who have been subjected to and who have already been infected with the HSV virus. The method claims of the Dori reference make this clear because they recite a method for treating a subject "having a disease". There is simply no recognition in Dori that the specific compounds shown therein would have any properties as a prophylaxis agent for HSV, much less, for HIV.

different viral form? therefore same compound could not treat both.. ??

No basis is found in Dori for surmising that the same compounds which exhibit a therapeutic effect on a patient already infected with the HSV virus would also have a prophylaxis effect. Rather, one skilled in this art would understand that once a virus has entered a cell or infected a patient, the virus itself is changed. It is this changed form of the virus (whatever that might be) that Dori has found is susceptible to treatment with Compound 96. However, the skilled artisan would not conclude that the same compound is effective to provide a prophylactic effect on that form of the virus prior to its infecting the subject.

Considered in its most favorable light, Dori may make it "obvious to try" Compound 96 as a prophylaxis measure. However, it is well established that "obvious to try" is insufficient to render a claimed method unpatentable.

During the interview, data was presented to the examiner to show the effect of Compound 96 on survival in a mouse genital HSV-2 model. Copies of Charts 1 and 2 showing the data are submitted herewith. Chart No. 1 shows a comparison of saline, 2% Acyclovir, 2% Compound 96 and 0.5% Compound 96 on survival in the mouse HSV-2 model. As shown, the survival rate for both concentrations of Compound 96 was essentially 100%, yet the survival rate for the saline control and the 2% Acyclovir dropped precipitously beginning at day 8. Acyclovir is a compound which is well known for the treatment of HSV-2 in subjects having the disease. Clearly, the compound which is used for treatment of the disease simply does not have the same effect as a prophylactic measure and one skilled in this art would have no reason to expect such properties merely from the fact that a compound is known as a treatment agent.

Not relevant to HIV

Chart No. 2 shows the effect of Compound 96 on virus replication in the genital tract in mice (HSV-2). As shown, both concentrations of Compound 96 in essence prevent virus replication whereas the compound ACV which is known as a viral treating agent does not have a significant effect on virus replication. Hereagain, compounds which are known for treatment of HIV simply did not exhibit a prophylactic effect on HSV-2.

This data clearly supports applicant's assertion that the skilled artisan would find no reason to conclude that because a given compound is effective in the treatment of an infected patient, that same compound would be effective when used in a prophylactic mode, i.e., prior to the patients being infected.

Accordingly, the examiner's rejection on these references for the reasons advanced in the Office Action are untenable and should be withdrawn. These claims are patentable

over the cited references and favorable reconsideration and prompt notice of allowance are earnestly solicited.

Respectfully submitted,
REED SMITH, LLP

By: _____
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July 13, 2001
375 Park Avenue, 17th Floor
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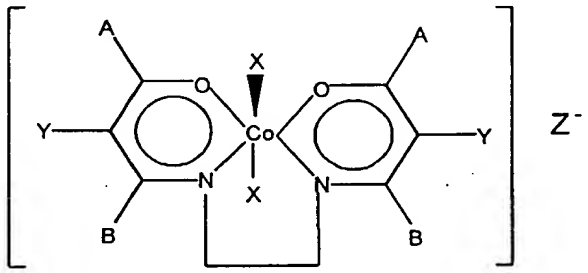
Tel. (212) 521-5400
JEG:ss
Encl.: Marked-up copy of amended claims 1, 6 and 11
Charts Nos. 1 and 2

Marked-up copy of amended claims:

--1. (Amended) A method for [preventing] prophylaxis of Human Immunodeficiency Virus infection in a subject comprising topically applying to the subject a composition comprising a Human Immunodeficiency Virus prophylactic effective amount of a compound having the structure



II

wherein each

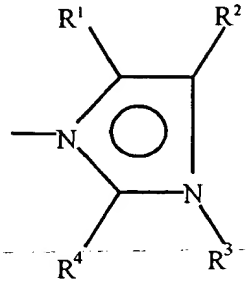
A may be the same or different and is an alkyl group, a phenyl group or a substituted derivative of a phenyl group;

Y may be the same or different and is hydrogen, an unbranched alkyl group, a halide or a group having the structure $R-\overset{\overset{O}{\|}}{C}-$ wherein R is hydrogen, an alkoxide group, an alkyl group, or OH;

B may be the same or different and each is hydrogen or an alkyl group;

Z^- is a soluble, pharmaceutically acceptable negative ion, and

X may be the same or different and is an axial ligand selected from the group consisting of moieties having the formula:



II a

wherein R^1, R^2, R^3, and R^4 may be the same or different and may be hydrogen or lower alkyl having from 1 to 4 carbon atoms;

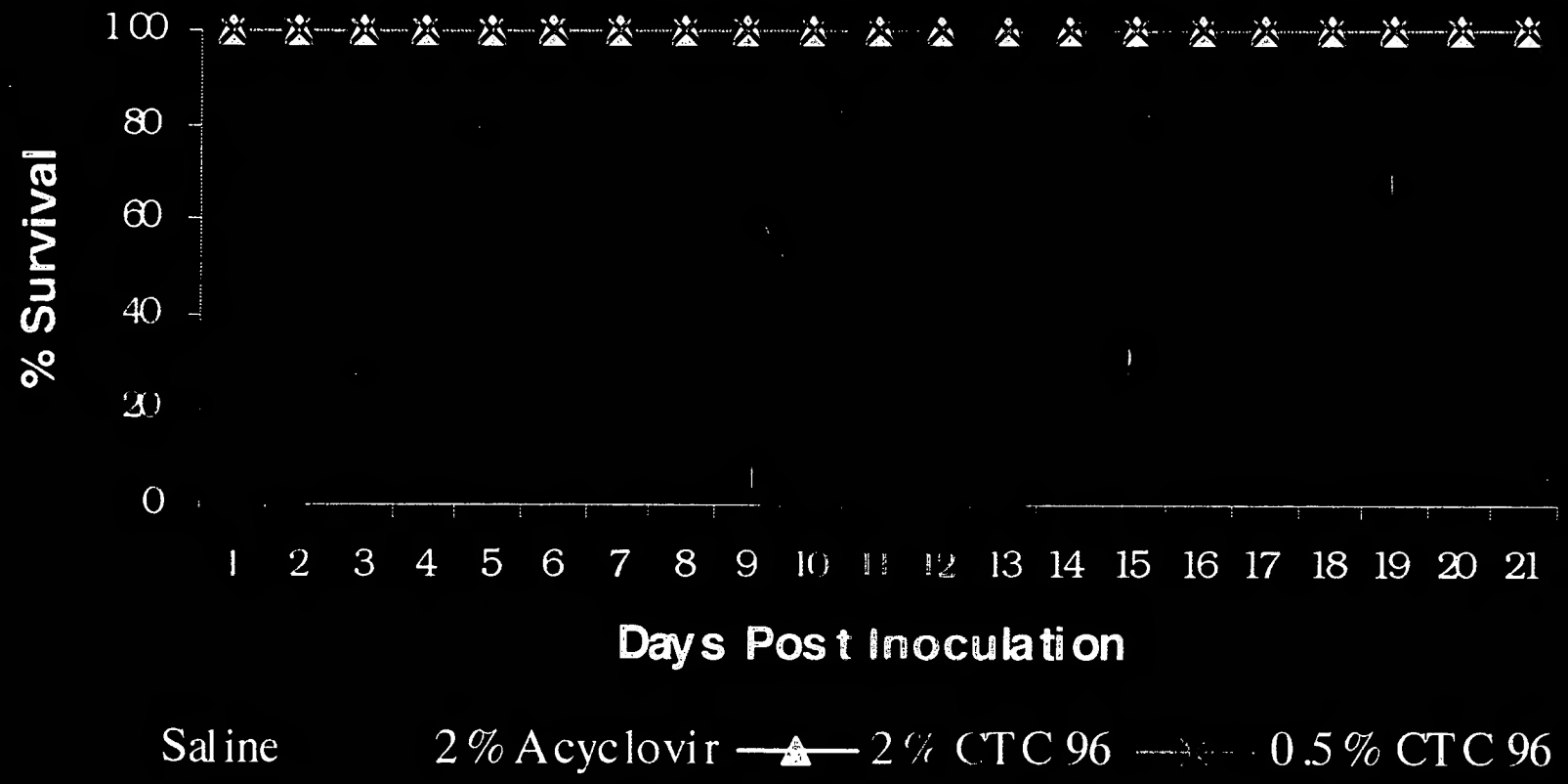
with the proviso that R^1, R^2, R^3, and R^4 are of a sufficiently small size so as not to prohibit the attachment of the axial ligand to the Co atom due to steric hindrance.--

--6. (Amended) The method of claim 1 wherein the composition is in the form of a pharmaceutically acceptable saline solution, salve, or creme [or the like].--

--11. (Amended) The method of claim 1 wherein the Human Immunodeficiency Virus [STRAINS???] is HIV-1 or HIV-2.--

Chart No. 1

Effect of CTC 96 on Survival in a Mouse Genital HSV-2 Model



Effect of CTC 96 on Virus Replication in the Genital Tract in Mice

Group	N	Virus Isolated	Vaginal Virus Titer	
			Day 1	Day 2
Saline	15	15	2.21 ± 0.27	3.64 ± 0.24
2.0% ACV	15	12	1.96 ± 0.38	3.82 ± 0.38
2.0% CTC 96	15	0	0	0
0.5% CTC 96	15	0	0	0

Virus titer calculated using only animals from which virus was isolated

$p<0.00001$ compared to saline controls by Fishers exact test